MAY - 6 2005

Nurse's Assistant® 1.7 O.R. Control System

March 28, 2005

510(k) #: K050829

SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Integrated Systems is hereby submitting the 510(k) Summary of Safety and Effectiveness for the Nurse's Assistant® 1.7 O.R. Control System.

A. Submitter:

ConMed Integrated Systems
Registration Number: 3031835

B. Company Contact:

C. Jeff Lipps
Director of Regulatory Affairs and Quality Assurance
1815 NW 169th Place, Suite 4020
Beaverton, OR 97006
503-614-1106 Phone
503-614-1109 Fax

C. Device Name:

Trade Name: Nurse's Assistant® 1.7 O.R. Control System

Common Name: Surgical Control Center

Classification Names:
1. 876.1500 – Endoscope and accessories
2. 878.4580 – Surgical lamp
3. 884.1720 – Gynecological laparoscope and accessories

Proposed Class/Device: Class II

Product Codes: GCJ, KOG, FET, FSY, HET, FTA

D. Predicate/Legally Marketed Devices:

1. Val Med Nurse's Assistant O.R. Control System – K010754
2. Olympus Integrated Endosurgery System EndoALPHA – K981993
3. Karl Storz OR1 (KSEA SCB-ACC) – K023704

E. Device Description:

The Nurse's Assistant® 1.7 O.R. Control System is a computerized control system that provides operating room (OR) staff with a simple touch panel interface from which to activate, adjust and monitor certain settings of equipment located in the OR.

Intended Use:

The Nurse's Assistant® 1.7 is intended to be used to route video from multiple sources to multiple destinations, to be used to turn on and off power to specific 110 volt receptacles within the OR, and to be used to adjust specific operating parameters of video displays, analog or digital recording, communication and playback equipment, endoscopic cameras, endoscopic light sources, surgical lamps, observation cameras, surgical cameras and operating room lights.

Indications for Use:

The Nurse's Assistant® 1.7 is indicated for use in an operating room for video assisted surgery. This includes minimally invasive procedures in all surgical specialties, as an adjunct display of interventional techniques and traditional open procedures.

The Nurse's Assistant® 1.7 is indicated for use in general, cardiovascular, ENT, gastroenterology, urology, plastic, obstetrics, gynecology, and orthopedic surgery, and general thoracoscopy, general cardiothoracic surgery, general laparoscopy, arthroscopy, laparoscopy, nasopharyngoscopy, ear endoscopy and sinusoscopy.

F. Substantial Equivalence / Device Technological Characteristics and Comparison to Predicate Device(s):

The Nurse's Assistant® 1.7 O.R. Control System has similar indications for use, intended use and technological characteristics as the predicate devices; Val Med Nurse's Assistant O.R. Control System – K010754, Olympus Integrated Endosurgery System EndoALPHA – K981993 and Karl Storz OR1 (KSEA SCB-ACC) – K023704.

The technological characteristics of the Nurse's Assistant® 1.7 are equivalent to the predicate devices listed above.

Tests performed on the Nurse's Assistant® 1.7 demonstrate substantial equivalence to the predicate devices listed above.

Conclusion:

The Nurse's Assistant® 1.7 is substantially equivalent to the predicate devices in terms of safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2005

Mr. C. Jeff Lipps
Director, Regulatory Affairs and Quality Assurance
ConMed Integrated Systems Incorporated
1815 NW 169th Place, Suite 4020
Beaverton, Oregon 97006

Re: K050829
Trade/Device Name: Nurse's Assistant® 1.7 O.R. Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 30, 2005
Received: May 2, 2005

Dear Mr. Lipps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050829

INTENDED USE / INDICATIONS FOR USE

510(K) # (if known): K050829

Device Name: Nurse's Assistant® 1.7 O.R. Control System

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] Devices

K050829

Prescription Use X OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)